REMARKS

This communication is responsive to the final Office Action dated July 25, 2008. Reconsideration of the present application is respectfully requested in view of the foregoing amendments and the remarks which follow.

I. Status of the claims

Claims 1-19 and 22-42 are withdrawn and claims 20, 21 and 44 are cancelled.

Claim 47 is amended to account for the cancellation of claim 44, from which it previously depended. No new matter is added.

Claim 43 is amended to incorporate therein subject matter of claim 44 and the specific sequence of the human IL-6 receptor. The specification cites to prior publications that list the amino acid sequence of the human IL-6 receptor, and how human IL-6 receptor was used to generate antibodies (*see, e.g.*, Example 4). This does not introduce new matter because the amino acid sequence of the human IL-6 receptor was already part of the knowledge available to those of ordinary skill in the art, at the time of filing, and was therefore already part of the application, *see, e.g.*, *Capon v Eshhar* 418 F.3d 1349 (Fed. Cir. 2006); *Falkner v. Inglis* 448 F.3d 1357 (Fed. Cir. 2006); *reh'g en banc den.*, 433 F.3d 1373 (2006); *cert den.* (Dkt No. 06-693, January 22, 2007).

The foregoing amendments are made solely to advance prosecution and without prejudice or disclaimer of any subject matter removed by amendment. Following the amendments, claims 1-19, 22-43, and 45-47 are pending, and claims 43 and 45-47 are under consideration.

II. Amendments to the specification

The specification is amended to add the sequence listing for SEQ ID NO:1, in accordance with 37 C.F.R. §§ 1.821-1.825.

III. Rejections under the enablement provision of 35 U.S.C. § 112, first paragraph

At pages 2-5 of the Office Action, claims 43-47 are rejected because the specification allegedly "does not reasonably provide enablement for a method of treating all inflammatory diseases by administering 'all' interleukin-6 receptor antibodies." Applicants respectfully traverse the rejection as applied to the pending claims.

The rejection has two aspects: (i) the treatment of "all inflammatory diseases" by administering (ii) "'all' interleukin-6 receptor antibodies." Both aspects rely on an overly expansive construction of the claim scope, which is particularly relevant when asserting that the claims exceed the scope of enablement provided by the specification.

As to the first aspect of the rejection, pending claim 43 does not claim a method of "treating all inflammatory diseases," as asserted, but the considerably more defined scope of a "method of treating *inflammatory bowel disease*, said method comprising administering to a subject in need thereof...." Properly construed, this aspect of the claim is commensurate with the enablement provided by the specification.

In regards the second aspect of the rejection, it is clear that the PTO considered that claim 43 read not only on antibodies against the IL-6 receptor, *per se*, but also gp130 (*see* rejection under 35 U.S.C. §§ 102, 103). To clarify that claim 43 concerns only antibodies against the human IL-6 receptor, *per se*, claim 43 has been amended to recite that the antibody "binds to interleukin-6 receptor having the [amino acid sequence of SEQ ID NO: 1]" SEQ ID NO: 1 is distinct from the sequence of gp130.

The person of ordinary skill can readily determine whether an antibody binds to a protein having the amino acid sequence of SEQ ID NO: 1, with only routine experimentation. Moreover, the specification has also demonstrated that antibodies that bind to SEQ ID NO: block signal transduction by IL-6, inhibit the biological activity of IL-6, and are suitable for treatment of inflammatory bowel by administration to a subject in need thereof. Therefore, the specific *structural features* present in an amino acid having the sequence of SEQ ID NO: 1 have been demonstrated as suitable immunogens for generating antibodies that block signal transduction by IL-6, inhibit the biological activity of IL-6, and are suitable for treatment of inflammatory bowel by administration to a subject in need thereof. Thus, once those

antibodies that bind to SEQ ID NO: 1 have been identified, the amount of screening required to determine which antibodies also block IL-6 signaling, *etc.*, is not undue. In view of the possession of the sequence together with the structure-function relationship established through the biological data set forth in the present specification, a person of ordinary skill in the art would be enabled to practice the presently claimed method across the full scope of claims without undue experimentation.

In conclusion, the pending claims have a defined and clearly circumscribed scope commensurate with the enablement provided by the specification, and not the expansive scope asserted to exceed such enablement. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

IV. Rejections under 35 U.S.C. § 102

At pages 5-6 of the Office Action, claims 43-44 and 47 are rejected as allegedly anticipated by WO 96/38481 to Burstein *et al.* ("Burstein"), which describes antibodies against gp130. Applicants respectfully traverse. Pending claim 43 is drawn to an anti-interleukin-6 receptor antibody that binds to an interleukin-6 receptor having an amino acid sequence of SEQ ID NO: 1. The human IL-6 receptor is distinct from gp130, and so Burstein's disclosure of antibodies against gp130 cannot anticipate the present claims. Reconsideration and withdrawal of the rejection is respectfully sought.

V. Rejections under 35 U.S.C. § 103

At pages 7-9 of the Office Action, claims 43-47 are rejected as allegedly unpatentable over Burstein in view of U.S. 5,530,101 to Queen *et al.* ("Queen"). Applicants respectfully traverse.

As an initial matter, neither Burstein nor Queen describe an anti-interleukin-6 receptor antibody which binds to interleukin-6 receptor having an amino acid sequence of SEQ ID NO: 1. Because the combination of references does not teach all elements of the claims, the claims are not obvious.

In addition, *even if* the combination of references did teach this missing element, there would be no obviousness because Burstein teaches away from the present invention by teaching that targeting gp130 has numerous advantages over targeting the IL-6 receptor. *See,*

e.g., Burstein at page 3, lines 2 to 10 "Although the potential role of the cytokines of this family in the aforementioned disorders remains to be elucidated, blockage of the common gp130 subunit offers the possible advantage that one or more members of the IL-6 family of cytokines may be inhibited by a single specific antagonist"; page 3, lines 16 to 21 "The potential advantage for anti-gp130 therapy rather than specific anti-IL-6 therapy is that targeting this receptor molecule may inhibit not only IL-6 effects but also cell growth that may in part be mediated by other cytokines that share the gp130 pathway;" and page 3, lines 25 to 30, "since gp130 is a portion of the receptor for a number of cytokine that promote the acute phase response (including interleukin-ll, leukemia inhibitory factor and oncostatin M), inhibition of that response with an antibody may well be employed as an antiinflammatory agent, since the acute phase response is part of the inflammatory process."

Accordingly, not only does the combination of references fail to provide all elements, there is *also* teaching away, and so the pending claims are respectfully believed to be nonobvious. Reconsideration and withdrawal of the rejection is sought.

VI. Obviousness-type double patenting

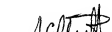
At pages 9-10 of the Office Action, claims 43-47 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-4 of U.S. Patent 6,723,319. Applicants respectfully request that this rejection be held in abeyance, pending the identification of otherwise allowable subject matter in the pending claims.

CONCLUSION

Applicants respectfully submit that the pending and non-withdrawn claims are in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions regarding the application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is hereby authorized to credit any overpayment, charge any additional fees which may be missing or which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition under 37 C.F.R. § 1.136 for such extension and authorize payment from Deposit Account No. 19-0741.

Respectfully submitted,

By 

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